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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/601,005	03/01/96	BACKSTROM K	06275/034001

HM22/1019

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EXAMINER	
BAWA, R	
ART UNIT	**PAPER NUMBER**
1619	17

DATE MAILED: 10/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/601,005	Backstrom et al.
Examiner	**Group Art Unit**
Mr. Raj Bawa	1619

☒ Responsive to communication(s) filed on *Dec 28, 1998 and August 14, 99.*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is clos d in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *46-83* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *46-83* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *13 14 16*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Detailed Action

(1) The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

(2) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 46 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Adjei et al (USP 5,676,931).

Adjei et al. identically discloses the drug aerosols recited in the above-mentioned claims. In other words, the composition of Adjei et al. disclose ingredients (NCFC propellants, a drugs and surfactant) that are identical to those recited in claims 46 and 76.

(3) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was

commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 46-61 and 64-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adjei et al. (USP 5,676,931).

Claims 62-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adjei et al. (USP 5,676,931) in view of Purewal et al. (USP 5,695,743).

As stated above, Adjei et al. disclose aerosol drug formulations analogous to those claimed herein by the applicants. The instant invention is directed forwards drug aerosols containing NCFCs, drugs and surfactant; additionally conventional solvents (ethanol) and carriers may be incorporated.

It is well known that all claimed ingredients are well known in the drug aerosol art. Furthermore, the method of mixing/ formulating (claims 74-75) the drug aerosol is conventional. The method of treating (claims 76-83) claimed is nominal and inherent to the aerosol composition itself. Hence, all the claims are directed forwards an aerosol composition per se. Additionally, note that the applicant's surfactant are functionally equivalent and hence may be substituted for each other. In fact, this is routinely done in this art as is evident from the tables/examples of the

cited art. This point is further established by a reading of the specification. Hence, the Examiner has not required a restriction requirement between the various surfactants recited.

In view of the above, it would be obvious to one of ordinary skill in the art at the time of the invention to select one of the functionally equivalent surfactants from Adjei's aerosol and obtain the specific aerosols claimed. In other words, since all the ingredients recited in claims 46-61 and 64-83 are disclosed by Adjei et al., it would be obvious to select a particular surfactant from the functionally equivalent list. desired. Purewal et al. has been relied to show the conventional use of ethanol in the drug aerosol art. Hence, it would be obvious for incorporate ethanol into the Adjei formulation and obtain the aerosols recited in claims 62-63.

Therefore, both the motivation and reasonable expectation of succe s is found in the prior art cited and a person having ordinary skill in the art would have arrived at the subject matter sought to be patented.

Additionally, note that (i) the cited art is analogous because it pertains to the field of the inventor's endeavor and is also reasonably pertinent to the particular problem with which the inventor's endeavor and is also reasonably pertinent to the particular problem with which the inventor is involved. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992); (ii) a comprising-type language does not exclude other steps, elements or materials. *Cues Inc. vs. Polymer Industries*, USPQ2d 1847 (DC ND GA 1988); (iii) it is well established that the claims are given the broadest interpretation during examination; (iv) a conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of

success; and (v) references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 U.S.P.Q. 545 (CCPA 1969).

In light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been obvious within the meaning of U.S.C. 1039(a).

(4) Claims of this application conflict with claims of Application No. 08/906,825; 08/736,267; 08/736,267; and 08/960,093. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

(5) The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

(6) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Raj Bawa whose telephone number is (703) -308-2423. The examiner can normally be reached on Tuesday thru Friday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash, can be reached on (703) -308-2328. The fax phone number for the organization where this application or proceeding is assigned is (703) -305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) -308-1235.

Bawa/LR

October 11, 2000

RAJ BAWA, Ph.D.
PRIMARY EXAMINER